



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2026
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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): sotatercept

Procedure No. PSUSA/00011076/202503

Period covered by the PSUR: 6 months to 24 March 2025



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for sotatercept, the scientific conclusions of PRAC are as follows:

In view of available data on pericardial effusion from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship with improvement of functional status or haemodynamics and in view of a plausible mechanism of action, the PRAC considers a causal relationship between sotatercept and pericardial effusion is at least a reasonable possibility. The PRAC concluded that the product information of products containing sotatercept should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for sotatercept the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sotatercept is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.